REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 43-70 will be pending in the application subsequent to entry of this Amendment.

This application is a divisional of earlier application Serial No. 09/958,328 which issued as U.S. patent 6,797,281 on September 28, 2004. The claims in this application are directed to the subject matter of Group II, namely claims 29-42 (original claims) according to the restriction requirement of July 11, 2003 in the parent application.

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention, to present them in appropriate claim format and to respond to the rejections stated in items 2 and 3 of the Official Action. The claims have been separated into methods of transporting drugs (43-53), methods of transporting cosmetics (claims 54-60) and composition comprising liposomes including a compound of formula II (claims 61-70).

Counsel observes that claims 29-42 presented in the Preliminary Amendment of July 23, 2003 include "use of ..." claims (29-39) and composition claims (40-42). Claim 40 distinguishes between transporting drugs and transporting cosmetics.

New claims 43-53 are based upon previous claims 29-39. Claims 54-60 are based upon previous claims 29-39 where the material being transported is a cosmetic. Claims 61-70 are based upon composition claims 40-42. Accordingly, the new claims presented above find basis in the original description as well as the claims as examined in the current Official Action.

In item 2, last sentence the examiner questions the wording of previous claim 32. Responsive to the examiner's question, the differences between citrate and acid citrate are in the protonation of one or more acidic function in the corresponding polyprotic acid (in other words, "not completed dissociation of the present acidic function").

In item 2, second paragraph, the examiner questions the last phrase used in previous claim 29. The claims have been revised and this expression has been removed considering rewording of the claims, thus this objection is moot.

It is respectfully submitted that the claims as above presented are compliant with 35 USC §112, first and second paragraphs. Withdrawal of the objections raised in the Official Action is requested.

The balance of the Official Action relates to two prior art-based rejections which appear to be directed to the "transport" aspect of previous claims 29-42. This means that of the new claims only claims 43-53 might be involved with respect to the examiner's statements with regard to the cited and applied prior art. As will be apparent, applicants have directed claims 43-53 to methods of transporting drugs which is quite distinct from procedures for transporting the delivery of genes. Accordingly, the anticipation rejection stated in item 5 of the Official Action is not pertinent to the claims now under review. Reconsideration and withdrawal is requested.

Previous claims 34-37 and 41 are rejected as being unpatentable/obvious over Wang et al, J. Med. Chem. 1998 in combination with U.S. 5,552,156 (Burke) and U.S. 5,008,288 (Stracher).

As noted above, claims 43-53 are directed to methods of transporting drugs using a liposome comprising the compound of formula II.

Concurring J. Med. Chem. 1998, on page 7 lines 6-8 of the present application applicants have already reported: *"In J. Med. Chem. 1998 Jun 18; 41(13):2207-15, a number of esters of L-carnitine useful for gene delivery are described,..."* (Emphasis added).

On page 8 lines 13-16 is reported: "*In the field of gene therapy or gene delivery, and drug delivery, there is therefore a strongly perceived need for stable, reproducible site-specific systems which are also active after a suitable period of time*" (Emphasis added).

J. Med, Chem. 1998, on page 2207, right column, last five lines reports *"Liposome prepared from these carnitine derivatives can efficiently complex with DNA ... and transfer..."* (Emphasis added).

It is well known by those skilled in the art that not all liposomes are able **to complex** DNA and/or **to crown** drugs. In fact, the capacity of a liposome to complex DNA and/or to crown a drug is not predictable *a priori.* In other words, are all the liposomes prepared using carnitine derivatives which are able to complex DNA also able to crown all camptothecin derivatives (drugs)? Persons skilled in the art know that the answer to this question is no. In fact, this expert knows that the capacity of a liposome to crown a drug depends on its shape and size. In J. Med. Chem, 1998 is never described nor suggested the use of compounds of formula

(II) for drug delivery. For these reasons J. Med. Chem. 1998 alone should not be considered applicable.

US 5,552,156 mentioned by the Examiner in the abstract reports: "The present invention provides water soluble, stable, highly pharmacologically active camptothecin drugs by solubilizing the camptothecin drugs in liposomes..."

Burke relates to liposomes of dimyristoyl phosphatidyicholin derivatives, and camptothecin derivatives such as "topotecan" (10-hydroxicamptothecin). The present invention relates to liposomes of carnitine derivatives, and camptothecin derivatives such as "gimatecan" (7-butoxyminomethylcamptothecin).

Camptothecin derivatives are known to be complex.

Those skilled in the art also knows that not all liposomes are able to crown camptothecin (drugs). As above mentioned, the art knows that the capacity of a liposome to crown a drug depends on its shape and size.

Reading US 5,552,156 it is apparent Burke is concerned with preventing hydrolysis and for stabilizing camptothecin (see column 2 lines 20-25). For these reasons Applicant respectfully considers that US 5.552.156 alone or in combination with Wang et al do not suggest any of the above claims.

US 5,008,288 (Stracher) cited by the Examiner relates to *"carnitine, aminocamitine and cysteic acid as carriers to bring pharmaceutically active compounds to desired sites in the body,...Carnitine derivatives are also incorporated into liposomes which are then used as carriers of active pharmaceutical agents"* (see the abstract).

The carnitine derivatives mentioned in US 5,008,288 are completely different from the carnitine derivatives claimed in the present application. This reference never mentioned or suggested the use of the carnitine derivatives of the structure claimed in the present application. For these reasons Applicants respectfully submit that US 5,008,288 alone or in combination with US 5.552.156 or J. Med. Chem, 1998 do not suggest any of the above claims.

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100